



Wyeth Pharmaceuticals
206 N Biddle Street
Marietta, PA 17547

Dennis J. Foley, Ph.D.
Vice President
Worldwide Regulatory Affairs
(845) 602-3122 tel
(845) 602-5621 fax
foleyd@wyeth.com

May 26, 2004

Mr. John Becher
Centers for Disease Control/Drug Service, D-09
1600 Clifton Road
Atlanta, GA 30333

**Re: STN 101106/5048 – Smallpox Vaccine Dryvax®
Extension of Dating**

Dear Mr. Becher:

Please note that Wyeth received approval on May 26, 2004 for BLA supplement 101106/5048 to extend dating from 18 to 21 months for the following lots of Smallpox Vaccine Dryvax® kits:

<u>Lot Number</u>	<u>New Expiration Date</u>
4020077	August 2004
4020076	August 2004
4030020	September 2004

Additional testing in accordance with the protocol filed to our license is planned and a CBE supplement will be filed to extend the expiration dating beyond 21 months, if appropriate.

Please note that the storage period of the vaccine after reconstitution with diluent continues to be 90 days.

Sincerely yours,

Dennis J. Foley, Ph.D.

DJF:jm

cc J. Grabenstein (DOD)
D. Staten (CBER)
D. Yeskey (CDC)